Decision Summary

Laparoscopic Sleeve Gastrectomy (LSG) for the treatment of obesity (BMI ≥ 35 kg/m^2) is covered only in randomized controlled trials (RCTs) meeting all of the following conditions:

The study must be designed to address the following outcomes:

Prospectively, in Medicare subjects who have BMI ≥ 35 kg/m^2 and qualify under the patient criteria specified in Medicare's Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination (NCD) (Section 100.1 Medicare National Coverage Determinations (NCD) Manual), what are the frequency and severity of the following outcomes and adverse events at 30 days, 90 days, 1 year, 2 year and 3 years or longer compared to subjects with the same patient criteria as above (see section 100.1 of the NCD manual) whose obesity treatment does not include laparoscopic sleeve gastrectomy:

- Mortality Rate
- Re-Operation Rate
- Adverse Events including stroke, myocardial infarction, leaks, infections and others
- Short and long term BMI
- Quality of Life
- Obesity-related comorbidities.

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
b. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
c. The research study does not unjustifiably duplicate existing studies.
d. The research study design is appropriate to answer the research question being asked in the study.
e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the FDA, it also must be in compliance with 21 CFR Parts 50 and 56.
g. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.
h. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.
i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
j. The clinical research study is registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.
l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, hereinafter 'The Act', the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

Any clinical studies under which there is coverage of LSG for the treatment of obesity (BMI ≥ 35 kg/m2) pursuant to this NCD must be approved within two years after the publication of the final decision memorandum for this policy. We chose the two year interval based on our prior experience with the timing of Coverage with Evidence Development (CED)-supported studies. If there are no approved clinical studies on this date, this NCD will expire. Clinical studies approved by the deadline shall continue to be subject to the terms of this NCD for no longer than five years to allow for completion of the study. The NCD can be reconsidered after that date.

Recognizing that this proposal regarding the appropriate sunset interval for this coverage decision should be subject to public review and comment, CMS welcomes comments or suggestions on the appropriate sunset time for CED-supported studies for laparoscopic sleeve gastrectomy.

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Proposed Decision Memo

TO: Administrative File: CAG-00250R2

FROM: Louis Jacques, MD
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SUBJECT: Proposed Decision Memorandum for CAG #00250R2
Bariatric Surgery for the Treatment of Morbid Obesity, Reconsideration for the Inclusion of Laparoscopic Sleeve Gastrectomy.

DATE: March 29, 2012

I. Proposed Decision

Laparoscopic Sleeve Gastrectomy (LSG) for the treatment of obesity (BMI ≥ 35 kg/m^2) is covered only in randomized controlled trials (RCTs) meeting all of the following conditions:

The study must be designed to address the following outcomes:

Prospectively, in Medicare subjects who have BMI ≥ 35 kg/m^2 and qualify under the patient criteria specified in Medicare's Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination (NCD) (Section 100.1 Medicare National Coverage Determinations (NCD) Manual), what are the frequency and severity of the following outcomes and adverse events at 30 days, 90 days, 1 year, 2 year and 3 years or longer compared to subjects with the same patient criteria as above (see section 100.1 of the NCD manual) whose obesity treatment does not include laparoscopic sleeve gastrectomy:

- Mortality Rate
- Re-Operation Rate
- Adverse Events including stroke, myocardial infarction, leaks, infections and others
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- Quality of Life
- Obesity-related comorbidities.

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
b. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
c. The research study does not unjustifiably duplicate existing studies.
d. The research study design is appropriate to answer the research question being asked in the study.
e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the FDA, it also must be in compliance with 21 CFR Parts 50 and 56.
g. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.
h. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.
i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
j. The clinical research study is registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.
l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
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Any clinical studies under which there is coverage of LSG for the treatment of obesity (BMI ≥ 35 kg/m2) pursuant to this NCD must be approved within two years after the publication of the final decision memorandum for this policy. We chose the two year interval based on our prior experience with the timing of Coverage with Evidence Development (CED)-supported studies. If there are no approved clinical studies on this date, this NCD will expire. Clinical studies approved by the deadline shall continue to be subject to the terms of this NCD for no longer than five years to allow for completion of the study. The NCD can be reconsidered after that date.

Recognizing that this proposal regarding the appropriate sunset interval for this coverage decision should be subject to public review and comment, CMS welcomes comments or suggestions on the appropriate sunset time for CED-supported studies for laparoscopic sleeve gastrectomy.

II. Background

The sleeve gastrectomy involves excision of the lateral aspect of the stomach, leaving a much reduced, lesser-curve based, tubular stomach (Hutter, 2011). Presently, LSG is commonly used as a stand alone approach to bariatric surgery; however, initially, the procedure served to reduce gastric capacity and initiate short-term weight loss while the malabsorptive component of the operation (biliopancreatic diversion) provided the long-term weight loss (Brethauer, 2010). A stand alone sleeve gastrectomy (SG) is sometimes referred to as an isolated sleeve gastrectomy (ISG). A laparoscopic approach to sleeve gastrectomy (LSG/LISG) was later developed. There are variations in the detail of the sleeve gastrectomy procedure itself. Although LSG has been gaining popularity over the last few years and the number of bariatric surgery units that offer it is increasing, there is not yet a standard technique for this procedure (Ferrer-Márquez, 2011).

Obesity, defined as a body mass index (BMI) ≥ 30 kg/m^2, is recognized as an important risk factor for morbidity and mortality associated with a number of chronic diseases such as heart disease and diabetes (Flegal, 2010). The Centers for Disease Control and Prevention (CDC) reported that obesity rates in the U.S. have increased dramatically over the last 30 years, and obesity is now epidemic in the United States (Kahn, 2009). For adults 60 years and older, the prevalence of obesity is about 37% among men and 34% among women (NHANES - National Health and Nutrition Examination Survey). Obesity may be further classified according to the National Institutes of Health (NIH):

- Class I Obesity = BMI 30.0-34.9 kg/m²
- Class II Obesity = BMI 35.0-39.9 kg/m²
- Class III (Extreme) Obesity = BMI ≥ 40.0 kg/m²

The prevalence of Class II and III obesity is about 12% among men and 13% among women aged 60 years and older (Flegal, 2010). With the trends in older adults, CMS recognizes the importance of screening and treating obesity and recently provided Medicare coverage for intensive behavioral therapy for obesity (NCD Manual Section 210.12 http://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf).

Past research has suggested that bariatric surgery may "resolve or improve CVD [cardiovascular disease] risk factors" (Heneghan, 2011). However, most past systematic reviews have not included stand alone laparoscopic sleeve gastrectomy (LSG). While the various forms of bariatric surgery may help improve health outcomes in some people, it is important to remember that the successful management of obesity is multi-pronged, life-long and goes well beyond bariatric surgery alone.

III. History of Medicare Coverage

In 2006, CMS released a final National Coverage Determination (NCD) on Bariatric Surgery for the Treatment of Morbid Obesity (NCD Manual Section 100.1 http://www.cms.gov/manuals/downloads/ncd103c1_Part2.pdf). For Medicare beneficiaries who have a BMI ≥ 35, at least one co-morbidity related to obesity, and who have been previously unsuccessful with medical treatment for obesity, the following procedures were determined to be reasonable and necessary:

- open and laparoscopic Roux-en-Y gastric bypass (RYGBP);
- laparoscopic adjustable gastric banding (LAGB); and
- open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS).

In addition, the NCD stipulates that the above bariatric procedures be covered only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (BSCOE) (Program Standards and requirements in effect on February 15, 2006). Due to lack of evidence at the time, the 2006 NCD specifically non-covered open vertical banded gastroplasty, laparoscopic vertical banded gastroplasty, open sleeve gastrectomy, laparoscopic sleeve gastrectomy, and open adjustable gastric banding. In 2009, CMS updated the NCD to include type 2 diabetes mellitus as a comorbidity.

A. Current Consideration

CMS opened this review to determine whether or not laparoscopic sleeve gastrectomy is reasonable and necessary under sections 1862 (a)(1)(A) and/or 1862 (a)(1)(E) of the Act. This analysis is limited to evaluating evidence to determine if LSG for the treatment of Class II and Class III obesity should be included as a covered use in the Bariatric Surgery for Treatment of Morbid Obesity National Coverage Determination (NCD). Since open sleeve gastrectomy is no longer reported on in the literature, we are not considering open sleeve gastrectomy within the scope of this reconsideration, thus it will remain non-covered. In addition, we are limiting our consideration to LSG conducted as a stand alone bariatric procedure, as the definitive treatment rather than one part of a two stage surgery. We believe that studies of LSG/SG as part of a two stage approach are not directly applicable since intent of surgery, patient selection, preparation and subsequent follow care are likely different for these individuals. As the American Society for Metabolic and Bariatric Surgery (ASMBS) noted, "the performance of the SG as the first stage of the laparoscopic procedure emerged as a risk reduction strategy for high-risk patients" (ASMBS, 2010). Since LSG is now predominately done as a stand alone procedure, LSG conducted as part of a planned two-stage surgery is beyond the scope of this analysis and thus shall remain non-covered. LSG that converts to open sleeve gastrectomy is also non-covered.

B. Benefit Category

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. An item or service must meet one of the statutorily defined benefit categories in the Social Security Act and not otherwise be excluded.

Under 1861(s)(1) bariatric surgery qualifies as a(n)

- physician service,
- Inpatient Hospital Services, and
- Incident to a physician's professional Service.

Thus, bariatric surgery qualifies as a benefit.

Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

IV. Timeline of Recent Activities

September 30, 2011	CMS initiates this national coverage analysis
October 30, 2011	The initial 30-day public comment period closes.
March xx, 2011	CMS publishes a proposed decision memorandum

V. Food and Drug Administration (FDA) Status

We are not aware of any FDA regulatory determinations on this surgical procedure.

VI. General Methodological Principles

When making national coverage decisions, under §1862(a)(1)(A), CMS generally evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix A. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. Public comments that contain personal health information will not be made available to the public. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

In this coverage analysis, we considered evidence for LSG as a planned stand alone procedure for the treatment of morbid obesity published since the prior decision on bariatric surgery in 2006. Important health outcomes of LSG include mortality, long term weight loss, impact on obesity related comorbidities, quality of life, reoperation, re-hospitalization and adverse events (such as stroke, myocardial infarction, staple line leaks, and infections). The long term benefits and harms should be considered since LSG is usually an elective, non-reversible procedure that will impact a patient's health for his or her remaining life. Outcomes at 5 years or longer would be desired.

B. Literature Search

CMS searched PubMed from 2/2006 (date of the last NCD) to 12/2011 using the key words sleeve or vertical gastrectomy. LSG is relatively new as a stand alone procedure as it previously has been done as the first part of a two stage surgery. We initially focused our search on randomized controlled trials (RCTs) that evaluated adults ≥ 65 years. Since no randomized controlled trials in older adults were found, we expanded the search criteria to include all RCTs, systematic reviews as well as large, multisite, prospective observational studies (sample size ≥ 100) on adults < 65 years with outcomes of weight loss after 2 years or longer, adverse events and reoperations. Excluded literature included very small observational studies with sample sizes less than 50 cases as they have inherent biases that substantially limit generalizability, and studies with follow-up of less than 1 year. Abstracts, presentations, articles not written in English and studies that evaluated biomarkers were also excluded.

Generally, CMS does not consider price when developing NCDs under 1862(a)(1)(A). Some of the studies included in our review evaluated cost-effectiveness; however, CMS' analysis did not rely on cost-effectiveness, nor did any cost effectiveness information impact the proposed decision.

C. Discussion of Evidence Reviewed

1. Question:

- *Is the evidence sufficient to determine that laparoscopic sleeve gastrectomy improves health outcomes for Medicare beneficiaries who have a BMI ≥ 35 kg/m2, at least one comorbidity of obesity and have been previously unsuccessful with medical treatment for obesity?*

2. External technology assessment

Colquitt JL, Picot J, Loveman E, Clegg AJ. Surgery for obesity. Cochrane Database Syst Rev 2009;2:CD003641.

In this review, only 2 RCTs (Himpens, 2006 and Karamanakos, 2008) met inclusion criteria. These studies evaluated weight loss as a health outcome. No LSG RCT evaluated mortality or focused on patients ≥ 65 years of age.

Colquitt and colleagues reported the results of a systematic evidence review "to assess the effects of bariatric surgery for obesity." Included studies were "RCTs, controlled clinical trials and prospective cohort studies comparing surgical interventions with non-surgical treatment (medical management or no treatment)" up to August, 2008. The target population included "adults fulfilling the standard definition of obese, i.e. people with a BMI of 30 or over" and "young people who fulfill the definition of obesity for their age, sex and height." Outcomes included "after at least 12 months follow-up: measures of weight change, fat content (for example body mass index) or fat distribution (for example waist-hip ratio); quality of life, ideally measured using a validated instrument; obesity related co-morbidities (for example diabetes, hypertension).

They reported: “Twenty six studies were included. Three RCTs and three prospective cohort studies compared surgery with non-surgical management, and 20 RCTs compared different bariatric procedures. The risk of bias of many trials was uncertain; just five had adequate allocation concealment. A meta-analysis was not appropriate. Surgery results in greater weight loss than conventional treatment in moderate (body mass index greater than 30) as well as severe obesity. Reductions in comorbidities, such as diabetes and hypertension, also occur. Improvements in health-related quality of life occurred after two years, but effects at ten years are less clear. Surgery is associated with complications, such as pulmonary embolism, and some postoperative deaths occurred. Five different bariatric procedures were assessed, but some comparisons were assessed by just one trial. The limited evidence suggests that weight loss following gastric bypass is greater than vertical banded gastroplasty or adjustable gastric banding, but similar to isolated sleeve gastrectomy and banded gastric bypass. Isolated sleeve gastrectomy appears to result in greater weight loss than adjustable gastric banding. Evidence comparing vertical banded gastroplasty with adjustable gastric banding is inconclusive. Data on the comparative safety of the bariatric procedures was limited. Weight loss and quality of life were similar between open and laparoscopic surgery. Conversion from laparoscopic to open surgery may occur.”

They concluded: “Surgery is more effective than conventional management. Certain procedures produce greater weight loss, but data are limited. The evidence on safety is even less clear. Due to limited evidence and poor quality of the trials, caution is required when interpreting comparative safety and effectiveness.”

Delaet D, Schauer D. Obesity in adults. Clinical Evidence 2011;03(604):1-25.

In this report, the systematic review by Colquit and colleagues appeared to be the main source of evidence on LSG.

Delaet and Schauer reported the results of a systematic evidence review “to answer the following clinical questions: What are the effects of drug treatments in adults with obesity? What are the effects of bariatric surgery in adults with morbid obesity?” Outcomes included mortality, weight loss and adverse events. Included studies were RCTs and systematic review up to September, 2010. For LSG, they reported: [Compared with gastric banding], “Sleeve gastrectomy may be more effective at increasing weight loss at 1 and 3 years (low-quality evidence). [Compared with gastric bypass], Sleeve gastrectomy seems more effective at increasing mean excess-weight loss at 1 to 2 years (moderate-quality evidence).” They noted that “we found no clinically important results from RCTs about sleeve gastrectomy compared with non-surgical treatment, or compared with vertical banded gastroplasty or biliopancreatic diversion in obese people.” They further noted that “we don't know whether sleeve gastrectomy is effective.”

ECRI Institute Health Technology Assessment Information Service. Emerging Technology Evidence Report: Laparoscopic sleeve gastrectomy for obesity. Plymouth Meeting (PA): ECRI Institute; February 2011. Available at: https://www.ecri.org/Documents/TA/Gastrectomy_CER.pdf
Summary at: https://www.ecri.org/Documents/Reprints/Laparoscopic_Sleeve_Gastrectomy_for_Obesity(Managed_Care)_October2011.pdf

In this systematic review, all comparative findings were rated inconclusive. Only 2 RCTs (Himpens, 2006 and Karamanakos, 2008) met inclusion and evaluated weight loss as a health outcome. No LSG RCT evaluated mortality or focused on patients ≥ 65 years of age.

The ECRI Institute conducted a systematic evidence review on LSG. Included studies were controlled studies published in English up to November, 2010. They identified 21 studies with 2633 patients and reported:

1. “How do clinical efficacy outcomes of LSG compare to other bariatric procedures?

No conclusions are currently possible regarding the comparative clinical efficacy of LSG because of the very small quantity of data, much of which came from small, low-quality studies.

An insufficient amount of evidence for each comparison was available to reach conclusions about how the effectiveness of LSG compares to other bariatric procedures.”

2. “How do perioperative outcomes of LSG compare to other bariatric procedures?

An insufficient amount of evidence for each comparison was available to reach conclusions about how perioperative outcomes associated with LSG compare to other bariatric procedures.”

3. “How do AE [adverse event] rates for LSG compare to those of other bariatric procedures?

No conclusions can be drawn regarding comparative safety because so few studies reported the same AEs.”

4. “What AEs were reported for LSG?

The overall mortality rate was 0.9 percent for super obese patients and 0.2 percent for morbidly obese patients (including one suicide). The proportion of patients requiring reoperation for any reason was 3.5 percent in the super obese group and 2.3 percent in the morbidly obese group. The most common AE was leaking, which most frequently occurred perioperatively. However, at less than 2 percent, the rate was low. The other AEs occurred at rates of less than 1 percent overall. Super obese patients had several instances of serious events that were not reported in the lower BMI patients, such as need for ventilator support or development of renal failure.”

Picot J, Jones J, Colquitt JL, Gospodarevskaya E, Loveman E, Baxter L, Clegg AJ. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. Health Technol Assess 2009;13:1-190, 215-357, iii-iv.

In this review, only 2 RCTs (Himpens, 2006 and Karamanakos, 2008) met inclusion criteria. These studies evaluated weight loss as a health outcome. No LSG RCT evaluated mortality or focused on patients ≥ 65 years of age.

Picot and colleagues reported the results of a systematic evidence review "to assess the clinical effectiveness and cost-effectiveness of bariatric surgery for obesity." The population included adult with body mass index (BMI) ≥ 30 kg/m^2. Outcomes included "after at least 12 months follow-up: measures of weight change; quality of life (QoL); perioperative and postoperative mortality and morbidity; change in obesity-related comorbidities; cost-effectiveness." Included studies were RCTs and controlled studies up to August 2008.

N.B. Although this evidence review uses the quality adjusted life year (QALY) framework, CMS has not adopted any specific QALY or similar threshold that is necessary for Medicare coverage.

They reported: "a total of 5386 references were identified of which 26 were included in the clinical effectiveness review: three randomised controlled trials (RCTs) and three cohort studies compared surgery with nonsurgical interventions and 20 RCTs compared different surgical procedures. Bariatric surgery was a more effective intervention for weight loss than non-surgical options. In one large cohort study weight loss was still apparent 10 years after surgery, whereas patients receiving conventional treatment had gained weight. Some measures of QoL improved after surgery, but not others.

After surgery statistically fewer people had metabolic syndrome and there was higher remission of Type 2 diabetes than in non-surgical groups. In one large cohort study the incidence of three out of six comorbidities assessed 10 years after surgery was significantly reduced compared with conventional therapy. Gastric bypass (GBP) was more effective for weight loss than vertical banded gastroplasty (VBG) and adjustable gastric banding (AGB). Laparoscopic isolated sleeve gastrectomy (LISG) was more effective than AGB in one study. GBP and banded GBP led to similar weight loss and results for GBP versus LISG and VBG versus AGB were equivocal. All comparisons of open versus laparoscopic surgeries found similar weight losses in each group. Comorbidities after surgery improved in all groups, but with no significant differences between different surgical interventions. Adverse event reporting varied. Mortality ranged from zero to 10%. Adverse events from conventional therapy included intolerance to medication, acute cholecystitis and gastrointestinal problems. Major adverse events following surgery, some necessitating reoperation, included anastomosis leakage, pneumonia, pulmonary embolism, band slippage and band erosion.

Bariatric surgery was cost-effective in comparison to non-surgical treatment in the reviewed published estimates of cost-effectiveness. However, these estimates are likely to be unreliable and not generalisable because of methodological shortcomings and the modeling assumptions made. Therefore a new economic model was developed. Surgical management was more costly than non-surgical management in each of the three patient populations analysed, but gave improved outcomes. For morbid obesity, incremental cost-effectiveness ratios (ICERs) (base case) ranged between £2000 and £4000 per quality adjusted life year (QALY) gained. They remained within the range regarded as cost-effective from an National Health Service (NHS) decision-making perspective when assumptions for deterministic sensitivity analysis were changed. For BMI ≥ 30 and < 40, ICERs were £18,930 at two years and £1397 at 20 years, and for BMI ≥ 30 and < 35, ICERs were £60,754 at two years and £12,763 at 20 years. Deterministic and probabilistic sensitivity analyses produced ICERs which were generally within the range considered cost-effective, particularly at the long twenty year time horizons, although for the BMI 30-35 group some ICERs were above the acceptable range."

They concluded: "Bariatric surgery appears to be a clinically effective and cost-effective intervention for moderately to severely obese people compared with non-surgical interventions. Uncertainties remain and further research is required to provide detailed data on patient QoL; impact of surgeon experience on outcome; late complications leading to reoperation; duration of comorbidity remission; resource use. Good-quality RCTs will provide evidence on bariatric surgery for young people and for adults with class I or class II obesity. New research must report on the resolution and/or development of comorbidities such as Type 2 diabetes and hypertension so that the potential benefits of early intervention can be assessed."

Klarenbach S, Padwal R, Wiebe N, Hazel M, Birch D, Manns B, Karmali S, Sharma A, Tonelli M. Bariatric Surgery for Severe Obesity: Systematic Review and Economic Evaluation [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2010 (Technology report;no. 129). [cited 2010-09-20]. Available from: http://www.cadth.ca/en/products/health-technology-assessment/publication/2667

Related publication:
Padwal R, Klarenbach S, Wiebe N, Birch D, Karmali S, Manns B, Hazel M, Sharma AM, Tonelli M. Bariatric surgery: a systematic review and network meta-analysis of randomized trials. Obes Rev 2011;12:602-21. doi: 10.1111/j.1467-789X.2011.00866.x. Epub 2011 Mar 28.

Klarenbach and colleagues reported the results of a systematic evidence review "to assess the evidence on clinical effectiveness and safety, and the economic implications of using different bariatric surgery methods in adult patients with severe obesity, as compared with standard care (i.e., lifestyle modification: diet and exercise medical counseling) with or without pharmacological therapy." The target population included "severely obese adults (16 years or older), with an accepted indication for bariatric surgery: BMI of 40 kg/m2 or more (or BMI of 35 kg/m2 or more with at least one obesity-related comorbidity)." Outcomes included "weight change (primary outcome), all-cause mortality, control of comorbidities, medication burden, hospitalization, health-related quality of life (QoL), excision of redundant tissue after weight loss (body contouring), joint operations, reoperations, gastrointestinal disturbances, and surgical sequelae." Included studies were quasi-randomized trials or RCTs up to February 2009.

They reported: "We identified 63 trials. Four trials compared a form of bariatric surgery to standard care, 31 compared one form of bariatric surgery to another form of bariatric surgery, and the remaining assessed a variant of a bariatric surgery. At one year, network analysis was used to rank the effectiveness in reducing BMI (from most to least efficacious): jejunoileal bypass, loop gastric bypass, mini-gastric bypass, BPD, sleeve gastrectomy, RYGB, horizontal gastroplasty (HG), vertical banded gastroplasty, adjustable gastric banding (AGB), and standard care. The results of network analysis at two and three to five years were similar. Of these procedures, sleeve gastrectomy, RYGB, and AGB are commonly performed in contemporary practice. The remaining procedures are uncommonly performed (e.g., BPD) or have been abandoned. Direct evidence supported mixed evidence findings for AGB compared with RGYB (direct evidence at one year: mean difference [MD] 5.8 kg/m2 [95% CI: 1.9 to 9.7]; at two years: 7.2 kg/m2 [5.5 to 8.9]; at three years to five years: 6.4 kg/m2 [4.9 to 7.9]). Direct evidence for sleeve gastrectomy did not show significant differences compared with other procedures or was unavailable. AGB was associated with a higher risk of slippage or dilation (risk difference [RD] 6.1% [1.3 to 11]) and procedure conversion or reversals (RD 8.3% [2.8 to 14]), and a lower risk of stenosis (RD 15% [8.3 to 22]), ulceration (RD 9.9% [4.0 to 16]), herniation (RD 4.5% [0.5 to 8.4]), and wound infection (RD 6.3% [1.4 to 11]) compared with RYGB. AGB was associated with shorter lengths-of-stay compared with RYGB (MD 1.7 days [1.3 to 2.0])."

They concluded: "The clinical review of effectiveness and safety found that although data from large, adequately powered, long-term RCTs are lacking, bariatric surgery seems to be more effective than standard care for the treatment of severe obesity in adults. Procedures that are mainly diversionary (for example, BPD) result in the greatest amounts of weight loss, hybrid procedures are of intermediate effectiveness (for example, RYGB), and restrictive procedures (for example, AGB) result in the least amounts of weight loss. RYGB and AGB tended to lead to trade-offs between the risk of adverse events and the need for procedure conversion or reversals. For sleeve gastrectomy, the evidence base was limited. The volume-outcome review found that higher surgical volumes were associated with better clinical outcomes. We were unable to identify thresholds for surgical volume that were associated with better clinical outcomes."

In this review, only 1 RCT (Karamanakos, 2008) met inclusion criteria. This study evaluated weight loss as a health outcome. No LSG RCT evaluated mortality or focused on patients ≥ 65 years of age.

3. Internal technology assessment

Birkmeyer NJ, Dimick JB, Share D, Hawasli A, English WJ, Genaw J, Finks JF, Carlin AM, Birkmeyer JD; Michigan Bariatric Surgery Collaborative. Hospital complication rates with bariatric surgery in Michigan. JAMA 2010;304:435-42.

Birkmeyer and colleagues reported the results of an analysis of the Michigan Bariatric Surgery Collaborative registry "to assess complication rates of different bariatric procedures and variability in rates of serious complications across hospitals and according to procedure volume and center of excellence (COE) status." The registry contains data voluntarily submitted from 25 hospitals that perform at least 25 bariatric procedures per year. All patients undergoing bariatric surgery from 6/2006 to 9/2009 (n = 15,275) were included. Patients undergoing revisional surgery and duodenal switch procedures were excluded. Main outcome was 30 day complication rate. Median age was 46 years. Median BMI was 46 kg/m^2. Men comprised 21% of the population. There were 854 sleeve gastrectomy (SG) procedures.

The authors reported: "Overall, 7.3% of patients experienced perioperative complications, most of which were wound problems and other minor complications. Serious complications were most common after gastric bypass (3.6%; 95%confidence interval [CI], 3.2%-4.0%), followed by sleeve gastrectomy (2.2%; 95% CI, 1.2% - 3.2%), and laparoscopic adjustable gastric band (0.9%; 95% CI, 0.6% - 1.1%) procedures (P< .001). Mortality occurred in 0.04% (95% CI, 0.001%-0.13%) of laparoscopic adjustable gastric band, 0 sleeve gastrectomy, and 0.14% (95% CI, 0.08% - 0.25%) of the gastric bypass patients." They concluded: "The frequency of serious complications among patients undergoing bariatric surgery in Michigan was relatively low. Rates of serious complications are inversely associated with hospital and surgeon procedure volume, but unrelated to COE accreditation by professional organizations."

In this analysis, there was no control group. There were no patients ≥ 60 years. Long term outcomes were not evaluated. The proportion of SGs that were single stand alone procedures was not reported. It was unclear if outcomes data were independently adjudicated.

DeMaria EJ, Pate V, Warthen M, Winegar DA. Baseline data from American Society for Metabolic and Bariatric Surgery-designated Bariatric Surgery Centers of Excellence using the Bariatric Outcomes Longitudinal Database. Surg Obes Relat Dis 2010;6:347-55. Epub 2010.

DeMaria and colleagues reported the results of an analysis of the Bariatric Outcomes Longitudinal Database (BOLD), "a registry of self-reported bariatric surgery patient information from the American Society for Metabolic and Bariatric Surgery Bariatric Surgery Center of Excellence participants" to describe baseline characteristics and initial outcomes. From June 2007 to May 2009, data from 57,918 patients were submitted by over 450 facilities. Mean age was about 47 years (5.67% were > 65 years). Men comprised 21% of the population. Mean BMI was about 46 kg/m^2. There were 1328 SG procedures. The author reported: "Through May 2009, 78 deaths were reported at any point after the index procedure, for a mortality rate of 0.13%. The 90-day mortality rate was 0.11%, and the 30-day mortality rate was .09%."

In this analysis, there was no control group. Long term outcomes were not evaluated. The proportion of SGs that were single stand alone procedures was not reported. Data by procedures were not reported. Data for older adults were not presented separately. It was unclear if outcomes data were independently adjudicated.

Himpens J, Dapri G, Cadière GB. A prospective randomized study between laparoscopic gastric banding and laparoscopic isolated sleeve gastrectomy: results after 1 and 3 years. Obes Surg 2006 Nov;16:1450-6.

Himpens and colleagues reported the results of a randomized trial "to compare the laparoscopic adjustable GB (LGB, also referred to as LAGB) and laparoscopic isolated SG in terms of weight loss, feeling of hunger, craving for eating sweets, gastroesophageal reflux disease (GERD), complications and re-operations, reporting the results after 1 year and 3 years." Eighty patients were randomized to LGB (n = 40) or LSG (n = 40). Inclusion criteria were not reported. Outcomes included weight loss and adverse events. Univariate Chi-square and Mann-Whitney tests were used for the analyses. Median age was 36 years (LGB) and 40 years (LSG). Gender was not reported. Median BMI was 37 for LGB versus 39 for LSG. The authors reported: "Median weight loss after 1 year was 14 kg (-5 to + 38) for GB and 26 kg (0 to 46) for SG (P < 0.0001); and after 3 years was 17 kg (0 to 40) for GB and 29.5 kg (1 to 48) for SG (P < 0.0001). Median decrease in BMI after 1 year was 15.5 kg/m2 (5 to 39) after GB and 25 kg/m2 (0 to 45) after SG (P < 0.0001); and after 3 years was 18 kg/m2 (0 to 39) after GB and 27.5 kg/m2 (0 to 48) after SG (P = 0.0004)." They concluded: "Weight loss and loss of feeling of hunger after 1 year and 3 years are better after SG than GB. GERD is more frequent at 1 year after SG and at 3 years after GB. The number of re-operations is important in both groups, but the severity of complications appears higher in SG."

In this study, the sample size was small. The number of patients ≥ 65 years of age was not reported but is likely to be very small given the median ages and age ranges. Surgeries were performed in 2002 and may or may not be identical to current LSG procedures in the United States. Patient characteristics and inclusion criteria, which are important for generalizability outside this one study site (Belgium), were not reported. Confidence intervals were not reported. Multivariate analyses to control for baseline factors, which are important in studies with small sample sizes, were not performed.

Hutter MM, Schirmer BD, Jones DB, Ko CY, Cohen ME, Merkow RP, Nguyen NT. First report from the American College of Surgeons Bariatric Surgery Center Network: laparoscopic sleeve gastrectomy has morbidity and effectiveness positioned between the band and the bypass. Ann Surg 2011;254:410-20.

Hutter and colleagues reported the results of an analysis of the American College of Surgeons Bariatric Surgery Center Network (ACS-BSCN) Accreditation Program "to assess the safety and effectiveness of the laparoscopic sleeve gastrectomy (LSG) as compared to the laparoscopic adjustable gastric band (LAGB), the laparoscopic Roux-en-Y gastric bypass (LRYGB) and the open Roux-en-Y gastric bypass (ORYGB) for the treatment of obesity and obesity related diseases." "The ACS-BSCN accredits facilities in the United States that have undergone an independent, voluntary and rigorous peer evaluation in accordance with nationally recognized bariatric surgical standards." From July 2007 to September 2010, data on 28,616 patients were voluntarily submitted by 190 hospitals. There were 944 LSG procedures. Of these, mean age was about 47 years (5.93% were ≥ 60 years). Men comprised about 25% of the population. Mean BMI was about 46 kg/m^2.

The authors reported: "The LSG has higher risk-adjusted morbidity, readmission and reoperation/intervention rates compared to the LAGB, but lower reoperation/intervention rates compared to the LRYGB and ORYGB. There were no differences in mortality. Reduction in BMI and most of the weight-related comorbidities after the LSG also lies between those of the LAGB and the LRYGB/ORYGB." They concluded: "LSG has morbidity and effectiveness positioned between the LAGB and the LRYGB/ORYGB for data up to 1 year. As obesity is a lifelong disease, longer term comparative effectiveness data are most critical, and are yet to be determined."

In this analysis, there was no control group. Long term outcomes were not evaluated. Data for older adults were not presented separately. It was unclear if outcomes data were independently adjudicated.

Karamanakos SN, Vagenas K, Kalfarentzos F, Alexandrides TK. Weight loss, appetite suppression, and changes in fasting and postprandial ghrelin and peptide-YY levels after Roux-en-Y gastric bypass and sleeve gastrectomy: a prospective, double blind study. Ann Surg 2008;247:401-7.

Karamanakos and colleagues reported the results of a randomized clinical trial "to evaluate and compare the effects of laparoscopic Roux-en-Y gastric bypass (LRYGBP) with laparoscopic sleeve gastrectomy (LSG) on body weight, appetite, fasting, and postprandial ghrelin and peptide-YY (PYY) levels." Inclusion and exclusion criteria were not reported. A total of 32 patients were randomly assigned to LRYGBP (n = 16) or LSG (n = 16). Measurements were recorded at months 1, 3, 6, and 12 postoperatively. Univariate Student t test was used for the analyses. Mean age was about 34 years. Men comprised about 16% of the study population. Mean baseline BMI was about 45 kg/m2.

They reported: "Body weight and body mass index (BMI) decreased markedly (P < 0.0001) and comparably after either procedure. Excess weight loss was greater after LSG at 6 months (55.5% +/- 7.6% vs. 50.2% +/- 6.5%, P = 0.04) and 12 months (69.7% +/- 14.6% vs. 60.5% +/- 10.7%, [P= 0.05])." They concluded: "PYY levels increased similarly after either procedure. The markedly reduced ghrelin levels in addition to increased PYY levels after LSG, are associated with greater appetite suppression and excess weight loss compared with LRYGBP."

In this study, the sample size was very small which greatly reduces the strength of the study. Patient characteristics and inclusion criteria, which are important for generalizability outside this one study site (Greece), were not reported. Timeframes of enrollment and surgeries were not reported. There were no patients > 55 years. Mortality and adverse events were not reported. Confidence intervals were not reported. Multivariate analyses to control for baseline factors, which are important in studies with small sample sizes, were not performed

4. MEDCAC

The MEDCAC was not convened for this review.

5. Evidence-based guidelines

Our research did not reveal any evidence-based guidelines for LSG. An Internet-based search of www.guideline.gov (i.e., the National Guideline Clearinghouse) using the search terms "sleeve gastrectomy," "bariatric surgery," or "obesity" did not reveal any LSG surgery-specific guidelines. The SAGES guideline for clinical application of laparoscopic bariatric surgery was found during the search. While the SAGES guidelines provided guidelines for specific bariatric surgeries (LBPD +\- DS, RGB, and AGB) it did not include guidelines for LSG. Instead, it included this statement: "LSG is validated as providing effective weight loss and resolution of comorbidities to 3 to 5 years (level II, grade C)". The Veterans Administration/Department of Defense (VA/DoD) clinical practice guideline for screening and management of overweight and obesity was returned in the search; however, it did not include LSG in their bariatric surgery recommendations and stated, "there is insufficient evidence to recommend for or against the routine use of bariatric surgery in those over 65 years of age and patients with a substantial surgical risk." In addition, there were guidelines for the prevention and management of obesity. http://www.healthquality.va.gov/obesity/obe06_final1.pdf

6. Professional Society Position Statements

American Society for Metabolic & Bariatric Surgery. Updated Position Statement on Sleeve Gastrectomy as a Bariatric Procedure. 2011. Available at: http://s3.amazonaws.com/publicASMBS/GuidelinesStatements/PositionStatement/ASMBS-SLEEVE-STATEMENT-2011_10_28.pdf

The American Society for Metabolic and Bariatric Surgery (ASMBS) posted an update of their position statement:

Summary and Recommendations.

"Substantial comparative and long-term data are now published in the peer-reviewed literature demonstrating durable weight loss, improved medical comorbidities, long-term patient satisfaction, and improved quality of life after SG. The ASMBS therefore recognizes SG as an acceptable option as a primary bariatric procedure and as a first stage procedure in high risk patients as part of a planned staged approach.

Based on the current published literature, SG has a risk/benefit profile that lies between the laparoscopic adjustable gastric band and the laparoscopic Roux-en-Y gastric bypass. As with any bariatric procedure, long-term weight regain can occur and, in the case of SG, this could be managed effectively with re-intervention. Informed consent for SG used as a primary procedure should be consistent with consent provided for other bariatric procedures and should include the risk of long-term weight gain. Surgeons performing SG are encouraged to continue to prospectively collect and report outcome data in the peer-reviewed scientific literature."

This update was posted on the ASMBS site but has not yet been published in a peer reviewed journal. Long term data were extracted from 6 single site observational studies all with small sample sizes (n < 50), high loss to follow-up (20 - 90%) and/or high rate of revisional surgery (> 20%).

7. Expert Opinion

Except as may be noted elsewhere in this memorandum, we have not received expert opinion on this issue.

8. Public Comments

Initial 30 day comment period

CMS requested public comments on the evidence speaking to the health outcomes attributable to the use of LSG in the Medicare population and comments that pertain to clinical studies falling under the Coverage with Evidence Development (CED) paradigm authorized by Section 1862(a)(1)(A) and Section 1862(a)(1)(E) of the Social Security Act.

CMS received 180 public comments. 179 of them supported the inclusion of LSG as a covered surgery in the bariatric surgery NCD. There were no comments specifically about CED, though one commenter offered, "the field of Bariatric Surgery is covered with surgical techniques that initially were felt to be the best approach, however later they were abandoned. I believe sleeve gastrectomy is a viable option. However, patients must be screened for reflux and not encouraged to have the surgery if they have reflux, since it can be aggravated. Patients must be informed that although without symptoms of reflux, that up to 1 in 5 patients may develop reflux and further surgery may be required to alleviate the problem. More years, up to 10 years will probably clarify how bad or good sleeve gastrectomy can be for the patients."

VIII. CMS Analysis

A. Introduction

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally by Medicare (§1862(l) of the Act).

In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, section 1862(a)(1) of the Social Security Act in part states, with limited exceptions, no payment may be made under part A or part B for any expenses incurred for items or services:

- Which, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A)), or
- In the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section. ((§1862(a)(1)(E)).

Section 1142 of the Social Security Act describes the authority of the AHRQ. Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which diseases, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically.

Section 1862(a)(1)(E) allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of Medicare beneficiaries. For your convenience, the 2006 CED guidance document is available at http://www.cms.gov/determinationprocess/downloads/ced.pdf.

As noted earlier, our review sought the answer to the question below. We have repeated it here for the convenience of the reader.

- *Is the evidence sufficient to determine that laparoscopic sleeve gastrectomy improves health outcomes for Medicare beneficiaries who have a BMI ≥ 35 kg/m2, at least one comorbidity of obesity and have been previously unsuccessful with medical treatment?*

Obesity is a risk factor for cardiovascular disorders and arthritis related conditions. However, many individuals who have a BMI ≥ 35 kg/m^2 are asymptomatic and may be relatively stable when the decision for surgery is considered. In these instances, the consideration of long term benefits and harms must be carefully done to ensure that there is a clinically meaningful benefit. Flum and colleagues (2005) noted that "patients aged 65 years or older had a substantially higher risk of death within the early postoperative period than younger patients." Long term evidence of at least 2 years (ideally, at least 5 years) is needed to demonstrate net benefit given the initial postoperative risk and the permanent, irreversible nature of the surgery.

Initially sleeve gastrectomy was performed as "the gastric component of the ASMBS-approved bariatric procedure of biliopancreatic diversion with duodenal switch and began its evolution as a primary operation with the observation that a single-stage laparoscopic duodenal switch in super obese patients with major co-morbidities demonstrated a high risk of complications and mortality" (ASMBS, 2010). In this situation, sleeve gastrectomy was considered "a risk reduction strategy for high-risk patients" (ASMBS, 2010). We do not believe evidence in this context is applicable to our analysis of LSG as a definitive, stand alone bariatric procedure for obesity. For our analysis, high quality evidence specifically on stand alone LSG is needed to determine if it improves health outcomes in the population of interest.

We did not find any RCTs that compared LSG to medical management or another bariatric surgery approach that focused on adults who were ≥65 years. Three bariatric surgery registry analyses (Birkmeyer, 2010, DeMaria, 2010 and Hutter, 2011) were published and included adults who were ≥65 years of age; however, results were not presented separately in these analyses.

Since the evidence specifically for older adults is very limited, we considered evidence on health outcomes in younger populations. There were 2 published RCTs (Himpens, 2006 and Karamanakos, 2008) which evaluated weight loss as a primary outcome but no published RCT evaluated mortality. Both trials had study limitations (risk of bias), such as small sample sizes (80 and 32, respectively) and single site enrollment (reducing generalizability), and did not report confidence intervals (possible imprecision). The RCT by Himpens reported 3 year outcomes while the RCT by Karamankos reported 1 year results. While RCTs are generally accepted as the most rigorous study design, these two RCTs would not be graded as high quality (Guyatt, 2011 and Balshem, 2011). The three registry analyses provided suggestive data that LSG is similar to other forms of bariatric surgery in terms of weight loss and adverse events at 1 year. However, inherent biases in registry analyses limit the strength of this evidence. In general, registry analyses are challenged to support confident conclusions due to inherent limitations which could include voluntary self reporting, confounding, incomplete follow-up and outcome adjudication. Without a randomized trial, registry studies provide insufficient evidence by themselves.

No published study reported long term outcomes with adequate numbers of participants to draw a robust conclusion. Long term outcomes are important in that obesity is a life-long condition. Ideally 5 year or longer results would be most informative since the surgery is not reversible. Several small case studies have been published (Appendix B) but were excluded due to limitations in methodology. Several published systematic evidence reviews (Colquitt, ECRI, Klarenbach, Picot) reported similar conclusions that the evidence on LSG was limited (only the studies by Himpens and Karamanakos met inclusion criteria).

Overall, there is insufficient evidence to determine that laparoscopic sleeve gastrectomy for Medicare beneficiaries with BMI ≥ 35 kg/m^2 improves health outcomes. There were no high quality studies or RCTs in older adults. Age is an important, previously established variable associated with morbidity and mortality from bariatric surgery (Flum, 2005 and Dorman, 2011). Due to potential differences in risk profiles, comorbidities and other factors that may affect ability to tolerate surgery (and negatively impact recovery), results from LSG studies in younger adults are difficult to generalize to older adults. As Flum and colleagues (2005) importantly noted, older adults had a "substantially higher risk of death" following other forms of bariatric surgery. Registry analyses suggest LSG is similar to the other procedures. It is unproven if and when (at what follow-up time after surgery is procedural mortality negated) there is a net mortality benefit from LSG in the Medicare population.

No studies reported outcomes at 5 years or greater. While the RCT by Himpens reported 3 year outcomes, most studies reported only 1 year results. Further research is clearly needed. This position is also consistent with the 2010 American Society for Metabolic and Bariatric Surgery (ASMBS) position statement that "a deficiency of long-term follow-up data remains in the published surgical reports to confirm the effectiveness of SG as a stand-alone intervention at ≥ 5 years." While the ASMBS revised its position statement in 2011 to state that "substantial comparative and long-term data are now published in the peer-reviewed literature demonstrating durable weight loss, improved medical comorbidities, long-term patient satisfaction, and improved quality of life after SG," this update was based upon data from 6 small case studies with limitations such as high number of loss to follow up and revisional surgeries after LSG that significantly reduce the strength of evidence.

While generalizability to the Medicare population is limited, two early RCTs, several small observational studies and 3 large registry analyses suggest that stand alone LSG holds promise for weight loss and improved health outcomes in younger adults. Results for older adults were not reported separately in the registry reports but would provide important additional information. While economic considerations were reported in the reviews by Picot (2009) and Klarenbach (2010), these data were not used in the analysis of the key evidence question.

CMS is interested in receiving and reviewing data and/or analyses focused on older adults from the applicable registries, encouraging publishing of those results to the extent that they can add to the publically transparent evidence base and inform our decisions. Though we may consider a wide breadth of evidence, CMS favors the use of published data to inform coverage decisions because we value public transparency.

Disparities

Obesity is increasing in older adults in general. Zamboni and colleagues noted: "The prevalence of overweight and obesity is increasing among older age groups in developed countries, in both sexes, all ages, all races, all educational levels, both smokers and nonsmokers; an increase in BMI has been observed even among people with the highest levels of BMI" (Zamboni, 2005). In the general population, the United States Preventive Services Task Force (USPSTF) noted that "obesity is especially common in African Americans, some Hispanic populations, and Native Americans and some health sequelae reflect similar ethnic differences." Hutter and colleagues (2011) reported that white patients comprised 67.48% of patients who underwent LSG. To establish confidence of the complete generalizability of this procedure and to develop evidence, CMS suggests Medicare beneficiaries who have a BMI ≥ 35 kg/m2, at least one comorbidity of obesity, have been previously unsuccessful with medical treatment for obesity and are interested in LSG surgery consider enrolling in a randomized controlled trial to receive LSG.

Summary

The persuasiveness and thus the evidentiary weight of the published clinical studies is limited by methodologic shortcomings as described above. We believe the currently available evidence does not permit us to confidently determine that laparoscopic sleeve gastrectomy for obesity improves health outcomes for Medicare beneficiaries who have a BMI ≥ 35 kg/m^2, at least one comorbidity of obesity and have been previously unsuccessful with medical treatment. Therefore we propose that this use is not reasonable and necessary under 1862(a)(1)(A) of the Act.

We believe that there is adequate assurance that the surgical procedure itself is safe when furnished by experienced, qualified surgeons in appropriate facilities. Obesity is a significant health problem in the Medicare beneficiary population, and we have previously reviewed evidence that supported coverage of other bariatric surgery procedures. Morbid obesity itself and the comorbid conditions commonly found in this population are frequent exclusion criteria in clinical trials and pose challenges to the design and successful completion of clinical trials.

Therefore we propose to support the development of further research on the effectiveness of LSG for Medicare beneficiaries who have a BMI ≥ 35 kg/m^2 and at least one comorbidity only when furnished in a randomized controlled trial under the coverage with evidence development paradigm. LSG has become a popular choice for obese individuals < 65 years. This proposed decision will allow certain eligible beneficiaries to receive LSG in controlled environments to ensure optimal care and will enhance the evidence base and aid Medicare patients and providers in important clinical decision making.

IX. Conclusion

The Centers for Medicare & Medicaid Services (CMS) proposes that the currently available evidence is insufficient to conclude that the bariatric surgery known as laparoscopic sleeve gastrectomy (LSG) for the treatment of obesity (BMI ≥ 35 kg/m2) improves long-term beneficiary health outcomes. We therefore propose that coverage for LSG is not reasonable and necessary under § 1862 (a) (1) (A) of the Social Security Act.

However, we believe new, emerging data suggest that LSG for the treatment of obesity (BMI ≥ 35 kg/m2) may possibly provide health benefits for Medicare beneficiaries. We propose to support the development of further research on the effectiveness of LSG. Thus, under §1862 (a)(1)(E) of the Act, we propose to cover LSG for the treatment of obesity (BMI ≥ 35 kg/m2) for patients with at least one comorbidity when furnished in an approved clinical study under CED. Since LSG is now predominately done as a stand alone procedure, LSG conducted as part of a planned two-stage surgery is beyond the scope of this analysis and thus shall remain non-covered. LSG that converts to open sleeve gastrectomy is also non-covered.

All coverage patient criteria listed in the National Coverage Determination (NCD) titled, Bariatric Surgery for the Treatment of Morbid Obesity (Section 100.1 Medicare NCD Manual) apply to this reconsideration. This decision would not modify existing requirements for any other covered or non-covered indication for Bariatric Surgery for the Treatment of Morbid Obesity NCD (Section 100.1 Medicare NCD Manual).

A randomized controlled trial under which there is CED for laparoscopic sleeve gastrectomy for the treatment of obesity (BMI ≥ 35 kg/m2) for patients with at least one comorbidity must address the following:

Prospectively, in Medicare subjects who have BMI ≥ 35 kg/m^2 and qualify under the patient criteria specified in Medicare's Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination (NCD) (Section 100.1 Medicare National Coverage Determinations (NCD) Manual), what are the frequency and severity of the following outcomes and adverse events at 30 days, 90 days, 1 year, 2 year and 3 years or longer compared to subjects with the same patient criteria as above (see section 100.1 of the NCD manual) whose obesity treatment does not include laparoscopic sleeve gastrectomy:

- Mortality Rate
- Re-Operation Rate
- Adverse Events including stroke, myocardial infarction, leaks, infections and others
- Short and long term BMI
- Quality of Life
- Oobesity-related comorbidities.

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
b. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
c. The research study does not unjustifiably duplicate existing studies.
d. The research study design is appropriate to answer the research question being asked in the study.
e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the FDA, it also must be in compliance with 21 CFR Parts 50 and 56.
g. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.
h. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.
i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
j. The clinical research study is registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.
l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions. Since assurance of patient safety is inherent in the above listed standards, the current criteria for CMS covered bariatric surgeries be performed in facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (program standards and requirements in effect on February 15, 2006) do not apply for LSG conducted within a clinical trial.

CMS further proposes that any clinical studies under which there is coverage of LSG for the treatment of obesity (BMI ≥ 35 kg/m2) pursuant to this NCD must be approved within two years after the publication of the final decision memorandum for this policy. Clinical studies approved by the deadline shall continue to be subject to the terms of this NCD for no longer than five years to allow for completion of the study. If there are no approved clinical studies within two years after the publication of the final decision memorandum, this NCD will expire and coverage LSG for the treatment of obesity (BMI ≥ 35 kg/m2) will revert to the coverage policy in effect prior to the issuance of the final DM for this NCD (Section 100.1 Medicare NCD Manual).

We are requesting public comments to this proposed decision pursuant to section 1862(l) of the Act. After consideration of the public comments and any additional evidence, we will issue a final determination responding to the public comments consistent with §1862(l)(3) of the Act. In addition, recognizing that the proposed sunset interval for a coverage decision should be subject to public review and comment, CMS encourages comments on the appropriate sunset time for CED-supported studies for LSG.

Appendix A: General Methodological Principles of Study Design

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine whether: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

CMS normally divides the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's risks and benefits.

The issues presented here represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has unique methodological aspects.

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.

- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.

- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.

- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.

- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias),

- Co-interventions or provision of care apart from the intervention under evaluation (confounding),

- Differential assessment of outcome (detection bias),

- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials,
- Non-randomized controlled trials,
- Prospective cohort studies,
- Retrospective case control studies,
- Cross-sectional studies,
- Surveillance studies (e.g., using registries or surveys),
- Consecutive case series,
- Single case reports.

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens, and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease, and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing, and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage decisions for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation), and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations because one of the goals of our determination process is to assess health outcomes. We are interested in the results of changed patient management not just altered management. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Improved health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. For most determinations, CMS evaluates whether reported benefits translate into improved health outcomes. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

Appendix B – Excluded Studies

Behrens C, Tang BQ, Amson BJ. Early results of a Canadian laparoscopic sleeve gastrectomy experience. Can J Surg 2011;54:138-43.

Bohdjalian A, Langer FB, Shakeri-Leidenmühler S, Gfrerer L, Ludvik B, Zacherl J, Prager G. Sleeve gastrectomy as sole and definitive bariatric procedure: 5-year results for weight loss and ghrelin. Obes Surg 2010;20:535-40. Epub 2010 Jan 22.

Chopra A, Chao E, Etkin Y, Merklinger L, Lieb J. Delany H. Laparoscopic sleeve gastrectomy for obesity: can it be considered a definitive procedure? Surg Endosc 2011 Dec 17. [Epub ahead of print]

D'Hondt M, Vanneste S, Pottel H, Devriendt D, Van Rooy F, Vansteenkiste F. Laparoscopic sleeve gastrectomy as a single-stage procedure for the treatment of morbid obesity and the resulting quality of life, resolution of comorbidities, food tolerance, and 6-year weight loss. Surg Endosc 2011;25:2498-504.

Himpens J, Dobbeleir J, Peeters G. Long-term results of laparoscopic sleeve gastrectomy for obesity. Ann Surg 2010;252:319-24.

Johnston D, Dachtler J, Sue-Ling HM, King RF, Martin G. The Magenstrasse and Mill operation for morbid obesity. Obes Surg 2003;13:10-6.

Leivonen MK, Juuti A, Jaser N, Mustonen H. Laparoscopic sleeve gastrectomy in patients over 59 years: early recovery and 12-month follow-up. Obes Surg 2011;21:1180-7.

Nath A, Leblanc KA, Hausmann MG, Kleinpeter K, Allain BW. Romero R. Laparoscopic sleeve gastrectomy: our first 100 patients. JSLS 2010;14:502-8. doi: 10.4293/108680810X12924466007809.

Sabbagh C, Verhaeghe P, Dhahri A, Brehant O, Fuksa D, Badaoui R, Regimbeau JM. Two-year results on morbidity, weight loss and quality of life of sleeve gastrectomy as first procedure, sleeve gastrectomy after failure of gastric banding and gastric banding. Obes Surg 2010;20:679-84.

Sarela AI, Dexter SP, O'Kane M, Menon A, McMahon MJ. Long-term follow-up after laparoscopic sleeve gastrectomy: 8-9-year results. Surg Obes Relat Dis. 2011 Jul 20. [Epub ahead of print]

Strain GW, Saif T, Gagner M, Rossidis M, Dakin G, Pomp A. Cross-sectional review of effects of laparoscopic sleeve gastrectomy at 1, 3, and 5 years. Surg Obes Relat Dis 2011;7:714-9.

Weiner RA, Weiner S, Pomhoff I, Jacobi C, Makarewicz W, Weigand G. Laparoscopic sleeve gastrectomy—influence of sleeve size and resected gastric volume. Obes Surg 2007;17:1297-305.

Zacharoulis D, Sioka E, Papamargaritis D, Lazoura O, Rountas C, Zachari E, Tzovaras G. Influence of the Learning Curve on Safety and Efficiency of Laparoscopic Sleeve Gastrectomy. Obes Surg 2011 May 12. [Epub ahead of print]

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Bibliography

American Society for Metabolic & Bariatric Surgery. Updated Position Statement on Sleeve Gastrectomy as a Bariatric Procedure. 2011. Available at: http://s3.amazonaws.com/publicASMBS/GuidelinesStatements/PositionStatement/ASMBS-SLEEVE-STATEMENT-2011_10_28.pdf.

Balshem H, Helfand M, Schünemann HJ, Oxman AD, Kunz R, Brozek J, Vist GE, Falck-Ytter Y, Meerpohl J, Norris S, Guyatt GH. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol 2011;64:401-6. Epub 2011 Jan 5.

Birkmeyer NJ, Dimick JB, Share D, Hawasli A, English WJ, Genaw J, Finks JF, Carlin AM, Birkmeyer JD; Michigan Bariatric Surgery Collaborative. Hospital complication rates with bariatric surgery in Michigan. JAMA 2010;304:435-42.

Brethauer SA. Sleeve gastrectomy. Surg Clin North Am 2011;91(6):1265-79.

Centers for Medicare and Medicaid Services. NCD Manual 100.1 (available at: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&ncdver=3&NCAId=160&ver=40&NcaName=Bariatric+Surgery+for+the+Treatment+of+Morbid+Obesity+(1st+Recon)&bc=AiAAAAAAIAAA&).

Centers for Medicare and Medicaid Services. NCD Manual 210.12 (available at: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=353&ncdver=1&NCAId=253&ver=6&NcaName=Intensive+Behavioral+Therapy+for+Obesity&bc=AiAAAAAAIAAA&).

Clinical Issues Committee of the American Society for Metabolic and Bariatric Surgery. Updated position statement on sleeve gastrectomy as a bariatric procedure. Surg Obes Relat Dis 2010;6:1-5. Epub 2009 Nov 17.

Colquitt JL, Picot J, Loveman E, Clegg AJ. Surgery for obesity. Cochrane Database Syst Rev 2009;2:CD003641.

Delaet D, Schauer D. Obesity in adults. Clinical Evidence 2011;03(604):1-25..

Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999-2008. JAMA 2010;303:235-421.

DeMaria EJ, Pate V, Warthen M, Winegar DA. Baseline data from American Society for Metabolic and Bariatric Surgery-designated Bariatric Surgery Centers of Excellence using the Bariatric Outcomes Longitudinal Database. Surg Obes Relat Dis 2010;6:347-55. Epub 2010.

Dorman RB, Abraham AA, Al-Refaie WB, Parsons HM, Ikramuddin S, Habermann EB. Bariatric Surgery Outcomes in the Elderly: An ACS NSQIP Study. J Gastrointest Surg 2011 Oct 27. PMID:22038414 [Epub ahead of print].

ECRI Institute Health Technology Assessment Information Service. Emerging Technology. Evidence Report: Laparoscopic sleeve gastrectomy for obesity. Plymouth Meeting (PA): ECRI Institute; 2011 October. Available at: https://www.ecri.org/Documents/TA/Gastrectomy_CER.pdf.
Summary at: https://www.ecri.org/Documents/Reprints/Laparoscopic_Sleeve_Gastrectomy_for_Obesity(Managed_Care)_October2011.pdf.

Ferrer-Marquez M, Belda-Lozano R, Ferrer-Ayza M. Technical controversies in Laparoscopic Sleeve Gastrectomy. Obes Surg. 2012 Jan;22(1):182-7.

Flum DR, Kwon S, MacLeod K, Wang B, Alfonso-Cristancho R, Garrison LP, Sullivan SD. Bariatric Obesity Outcome Modeling Collaborative. The use, safety and cost of bariatric surgery before and after Medicare's national coverage decision. Ann Surg 2011;254:860-5.

Flum DR, Salem L, Elrod JA, Dellinger EP, Cheadle A, Chan L. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. JAMA 2005;294:1903-8.

Guyatt GH, Oxman AD, Kunz R, Atkins D, Brozek J, Vist G, Alderson P, Glasziou P, Falck-Ytter Y, Schünemann HJ. GRADE guidelines: 2. Framing the question and deciding on important outcomes. J Clin Epidemiol 2011;64:395-400. Epub 2010 Dec 30.

Heneghan HM, Meron-Eldar S, Brethauer SA, Schauer PR, Young JB. Effect of bariatric surgery on cardiovascular risk profile. Am J Cardiol 2011;108:1499-507.

Himpens J, Dapri G, Cadière GB. A prospective randomized study between laparoscopic gastric banding and laparoscopic isolated sleeve gastrectomy: results after 1 and 3 years. Obes Surg 2006 Nov;16:1450-6.

Hutter MM, Schirmer BD, Jones DB, Ko CY, Cohen ME, Merkow RP, Nguyen NT. First report from the American College of Surgeons Bariatric Surgery Center Network: laparoscopic sleeve gastrectomy has morbidity and effectiveness positioned between the band and the bypass. Ann Surg 2011;254:410-20.

Karamanakos SN, Vagenas K, Kalfarentzos F, Alexandrides TK. Weight loss, appetite suppression, and changes in fasting and postprandial ghrelin and peptide-YY levels after Roux-en-Y gastric bypass and sleeve gastrectomy: a prospective, double blind study. Ann Surg 2008;247:401-7.

Klarenbach S, Padwal R, Wiebe N, Hazel M, Birch D, Manns B, Karmali S, Sharma A, Tonelli M. Bariatric Surgery for Severe Obesity: Systematic Review and Economic Evaluation [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2010 (Technology report;no. 129). [cited 2010-09-20]. Available from: http://www.cadth.ca/en/products/health-technology-assessment/publication/2667.

Padwal R, Klarenbach S, Wiebe N, Birch D, Karmali S, Manns B, Hazel M, Sharma AM, Tonelli M. Bariatric surgery: a systematic review and network meta-analysis of randomized trials. Obes Rev 2011;12:602-21. doi: 10.1111/j.1467-789X.2011.00866.x. Epub 2011 Mar 28.

Picot J, Jones J, Colquitt JL, Gospodarevskaya E, Loveman E, Baxter L, Clegg AJ. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. Health Technol Assess 2009;13:1-190, 215-357, iii-iv.

National Institutes of Health, National Heart, Lung and Blood Institute: Classification of Overweight and Obesity by BMI, Waist Circumference, and Associated Disease Risks. Accessed via http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/bmi_dis.htm.

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